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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/531,822	10/24/2005	Mark Brister	PA1187	3938

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MEDTRONIC VASCULAR, INC.
IP LEGAL DEPARTMENT
3576 UNOCAL PLACE
SANTA ROSA, CA 95403

EXAMINER	
HOUSTON, ELIZABETH	

ART UNIT	PAPER NUMBER
3731	

NOTIFICATION DATE	DELIVERY MODE
11/10/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

rs.vasciplegal@medtronic.com

Office Action Summary	Application No.	Applicant(s)	
	10/531,822	BRISTER, MARK	
	Examiner	Art Unit	
	ELIZABETH HOUSTON	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 August 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-6 and 8-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 3-6, 8-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

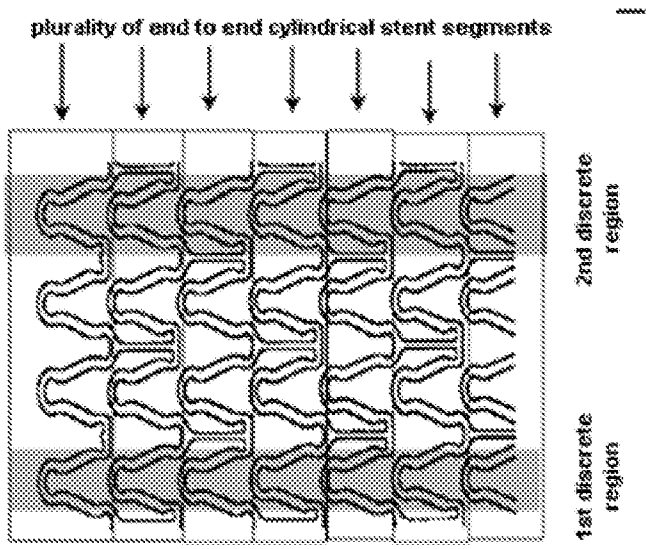
Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 1, 3-6, 8-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Castro et al (US 6,616,765) in view of Ragheb (US 5,873,904).

3. Castro discloses the invention substantially as claimed comprising a catheter, a balloon operably attached to the catheter, a stent disposed on the balloon (col. 1, lines 19-27) and a coating (10,80). The stent has a plurality of end to end longitudinally adjacent cylindrical stent segments (See Fig. 6a), the axis of the stent segments lying along a longitudinal axis. The stent has a first discrete region and second discrete region continuous over at least one pair of adjacent cylindrical segments (see below). The coating includes a first coating section comprising a first polymer including a first therapeutic agent (10) and a second coating section comprising a second polymer including a second therapeutic agent (80), the first polymer being different from the second polymer (C17:L61-C18:L5). The first and second regions can form a striped, spotted or ring pattern (see below depicting a striped pattern and note that the choosing of regions is subjective and not limited by the claims).



4. Castro does not explicitly disclose the first coating section is a single layer directly adjacent to and completely covering the outer surface in the first region and the second coating section is a single layer directly adjacent to and completely covering the outer surface in the second region. Castro does not explicitly disclose the first polymer being directly adjacent to the outer surface of the stent as a first coating section and the second polymer being directly adjacent to the outer surface of the stent as a second coating section. However Ragheb discloses a coated stent that incorporates the concept of applying coatings in different patterns including applying in parallel lines, particularly where two or more bioactive material are applied to the same surface indicating a first coating section being discrete from a second coating section. Since Castro depicts many different variations of drug coating patterns (see 7a-16b), it would have been obvious to one having ordinary skill in the art at the time of the invention to apply the teachings of Ragheb to incorporate a pattern that includes distinct parallel

lines for each material such that each material is adjacent to the outer surface of the stent and each coating section is discrete.

5. Castro does not explicitly disclose that the first region has a longitudinal length greater than the diameter of the stent in an expanded stent. However, it would be obvious to vary the length of the stent and the diameter of the stent to result in a stent where the length is greater than the diameter, since it is well known that the length and diameter will need to be varied depending on where the stent is intended to be delivered. Since the first regions can extend the length of the stent as depicted above, and the length can be modified to be greater than the diameter of the stent, the modified Castro will have a region that has a longitudinal length greater than the diameter of the stent in an expanded state. Since applicant failed to traverse examiner's assertion, the common knowledge or well-known in the art statement is taken to be admitted prior art (MPEP 2144.03 C).

6. Regarding claim 23, modified Castro does not explicitly disclose that the first region and the second region are separated by a bare section. However both Castro and Ragheb disclose various configurations that incorporate more that one coating as state above. Ragheb further discloses that portions of the stent would not be coated (C19:L64-67). Thus, it would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate bare sections of stent in between coated sections as suggested by Ragheb. Doing so would provide the advantage of providing drug to certain parts of the vessel (such as near a lesion) while not providing drug to another part of the vessel (such as near healthy tissue). A person of ordinary skill has

good reason to pursue the known options within his or her technical grasp if it yields predictable results.

Regarding claims 24 and 25, Castro discloses the invention substantially as claimed above except for exact dimensions of the bare section. It would have been obvious to one having ordinary skill in the art at the time the invention was made to vary the size of the bare section based on the size of the vessel and size of the lesion being treated. It has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch* 617 F.2d 272,205 USPQ 215 (CCPA 1980). A person of ordinary skill has good reason to pursue the known options within his or her technical grasp if it yields predictable results.

7. Regarding claims 11 and 18, Castro further discloses mixing a first polymer and first therapeutic agent with a first solvent to form a first polymer solution (col. 11, lines 7-13), applying the first polymer solution to the first region to form a first coating section of a coating completely covering the outer surface of the longitudinal adjacent cylindrical stent segments in the first region (col. 14, lines 65-67), mixing a second polymer and second therapeutic agent with a solvent to form a second polymer solution (col. 17, line 62 – col. 18, line 4), and applying the second polymer solution to the second region to form a second coating section of the coating completely covering the outer surface of the longitudinal adjacent cylindrical stent segments in the second region (col. 18, lines 14-32). The modification taught by Ragheb above incorporates the step of applying the first polymer solution directly to the stent in the first region and applying the second polymer solution directly to the stent in the second region.

8. Castro fails to specifically disclose that the solvent mixed with the second polymer and second therapeutic agent is a second solvent, but teaches that it could be a second solvent (col. 11, lines 55-59; col. 12, lines 20-24). Choosing a solvent based on the polymer chosen implies that if a second polymer is used, then a second solvent will also be used. Further, Castro discloses that all other variables of the second composition are different than that of the first, so it would have been obvious to choose a second solvent when forming the second polymer solution. Since applicant failed to traverse examiner's assertion, the common knowledge or well-known in the art statement is taken to be admitted prior art (MPEP 2144.03 C).

9. Regarding claims 12 and 19, Castro further discloses the first and second polymer solutions may be applied simultaneously (col. 17, lines 61-64). Regarding claims 13 and 20, Castro discloses curing the first and second polymer solutions (col. 9, lines 64-65). Regarding claims 14 and 21, Castro further discloses mounting the stent in a coating fixture and spraying the first polymer solution on the first region (col. 6, lines 24-35). Regarding claims 15-17, Castro further discloses mounting the stent in a coating fixture which is a computerized numerically controlled machine (column 7, lines 12-36), and spraying the first polymer solution on the first region by spraying, inkjet spraying, or inkjet printing (column 7, lines 42-45).

Response to Arguments

10. Applicant's arguments filed 08/27/10 have been fully considered but they are not persuasive.

11. Applicant argues that Ragheb fails to describe what the arms or tips are and therefore also fails to define a first polymer directly adjacent to the outer surface of the stent in a discrete first region and a second polymer directly adjacent to the outer surface of the stent in a discrete second region. Examiner finds this argument unconvincing. Firstly, Ragheb describes the arms at C18:L10-11 in addition to the fact that one of ordinary skill would easily be able to establish what the arms and tips of the stent are. Further, definition of the arms and tips are not completely relevant to the teaching used in the combination. What is relevant is that Ragheb teaches that more than one bioactive ingredient can be applied “in parallel lines” "to the same surface", in addition to applying bioactive material in “specific geometric patterns” or applying bioactive material to one portion and not to another. One of skill in the art could look to Ragheb and understand the advantage and desire of applying more than one bioactive material directly to the surface of the stent in different patterns around the stent.

12. It is noted that one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Castro clearly discloses the advantage of applying two coatings where each includes a polymer and therapeutic agent. The coatings are applied in many various configurations that allow the user to decide which configuration is best for the desired outcome. Castro does not disclose each of the coatings applied directly to the surface of the stent. Ragheb also teachings the advantage of applying more than one coating of therapeutic agent to the stent. Ragheb further teaches that

both coatings can be applied directly to the outer surface of the stent in various patterns. Thus one of ordinary skill would be able to look to the two references and come up with the claimed structure and method.

Conclusion

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Elizabeth Houston
/EH/
Examiner, Art Unit 3731

/Anhtuan T. Nguyen/
Supervisory Patent Examiner, Art Unit 3731
11/05/10